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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/110,376 05/12/98 COHEN

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THE LAW OFFICE OF JAMES C SIMMONS
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HM22/0214

EXAMINER

CANELLA, K

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/110,376

Applicant(s)

Cohen et al

Examiner

Karen Canella

Group Art Unit

1642



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- ☒ Claim(s) 1 _____ is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1 _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1642

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claim 1 has been amended and is under consideration.

New Claim Rejections

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for determining if a metastatic event has already occurred from a solid non-lymphoid primary tumor, is not enabling for a method of predicting the metastatic potential of a solid non-lymphoid primary tumor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Claim 1 is drawn to a method of predicting the lymphotropic metastatic potential of a solid non-lymphoid primary tumor comprising measuring the percentage of tumor cells which express TCR-beta, CD3, CD4, CD8, and zap-70, wherein the metastatic potential of the tumor is predicted to be low when no tumor cells are expressing TCR-beta, CD3, CD4, CD8 or zap-70. The specification teaches on pg. 5 and in figure 21, that a primary tumor taken from a patient already suffering with multiple auxiliary lymph node metastases exhibits staining for CD3 and beta F1. The specification further teaches on pg. 5 and figure 21, that metastatic tumor cells taken from another patient exhibited staining for CD3 and beta F1. The specification is thus enabling for a method of diagnosing metastatic disease that has already occurred. The specification does not demonstrate an interval of time between expression of a T-cell antigen and the metastatic event, wherein such interval of time the tumor expressing the T-cell antigen can be considered as having "metastatic potential" without the metastatic event having already occurred. Thus the specification has established a diagnostic method for evaluating if a metastatic event has already occurred, but has failed to establish a prediction of possible metastatic potential.

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Claim Rejections Withdrawn

4. All other rejections and objections as recited in Paper No. 12 are withdrawn.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

February 11, 2001



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